

Appln No. 09/650,482

Amdt date December 10, 2003

Reply to Office action of September 10, 2003

REMARKS/ARGUMENTS

This Response is in reply to the Office action of September 10, 2003. Claims 1-27 are pending in the application.

Claims 1-16

On page 4 of the action, claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,845,255 issued to Mayaud and U.S. Patent No. 5,924,074 issued to Evans. Applicant respectfully traverses this rejection.

The action, on page 4, further indicates that "Mayaud did not teach, wherein the service center server supplies the pharmacy server at least one of the plurality of formulary records upon request by a pharmacy client system when an order is processed." The action also suggests that "Evans discloses, wherein the service center supplies the pharmacy server at least one of the plurality of formulary records upon request by a pharmacy client system when an order is processed (col. 11, lines 65-67, col. 12, lines 1-15 and lines 56-67, col. 13, lines 1-30 and fig. 24 (406, 408, 410, 414, 416, 418, 430, 432 & 434))."

However, Evans, in col. 11, line 65 - col. 12, line 15, at most describes a "healthcare provider similarly accesses the medication manager 302 (FIG. 18) by clicking on a medication button 192 (FIG. 19) ... the medication button 314 activates a medication manager window 350. The physician can review the patient's history by viewing the medication history box 351 and the diagnosis history box 352 before prescribing any new

Appln No. 09/650,482

Amdt date December 10, 2003

Reply to Office action of September 10, 2003

medications ... the physician prescribes the medications listed in the selection box 356 by clicking on the prescribe button 357."

Evans further describes in col. 13, lines 1-29 and FIG. 24, that "a LAN 400 includes a backup server 426 and several peripherals ... Healthcare providers may access the LAN 400 using a desktop computer 416, a laptop computer 418 or wireless pen computer 420 ... Thus, a healthcare provider located in Boston, Mass. may access a patient record resident on the Scripps Health server 41, located in San Diego, Calif., using a web browser 412 ... communicating with a Web server in Boston, Mass."

Thus, Evans does not describe or suggest supplying a formulary record or a service center server supplying the pharmacy server a formulary record "upon request by a pharmacy client system when a order is processed" provided for in claim 1. Accordingly, a *prima facie* case of obviousness cannot be established because the fundamental features recited in claim 1 is absent and not suggested in the cited references.

Furthermore, individually, each of the references provides a complete solution. Specifically, Mayaud provides a complete solution to provide a electronic prescription management system. Likewise, Evans, provides a complete solution to provide medical records electronically. Hence, there is no motivation, suggestion or teaching to improve upon the complete solutions of Mayaud or Evans to arrive at the claimed invention. Moreover, there is no teaching or suggestion as to how to combine the prescription management system of Mayaud with the electronic medical records system of Evans to result in the claimed invention, specifically as recited in claim 1. Thus, claim 1 is believed to be patentable.

Appln No. 09/650,482

Amdt date December 10, 2003

Reply to Office action of September 10, 2003

Since claims 2-27 depend respectively from independent claim 1 and thus incorporate the features recited in this claim and contain additional limitations that, when considered as a whole are patentably distinguishable over the references of record, claims 2-27 are also believed to be patentable.

Furthermore, **claim 2** recites a plurality of order records where each order record includes order information for an order accepted and processed by the at least one pharmacy client system. The action, on page 5, indicates that Mayaud teaches these features and cites col. 20, lines 32-40. However, Mayaud, in col. 20, lines 32-39, at most describes "a patient problem history information screen ... in which a historical record of the patient's individual symptoms and diagnoses is listed and to which new problem reports can be posted" and that "desired personal or drug records relevant to possible allergies of this patient may be summoned from the host computer facility."

Thus, Mayaud, as cited above, describes "a historical record of patient's individual symptoms and diagnoses" and does not describe or suggest order information for an order accepted and processed by a pharmacy client system or a plurality of order records each including order information. Accordingly, a *prima facie* case of obviousness cannot be established because the fundamental features recited in claim 2 is absent and not suggested in the cited references. Also, none of the cited references contain any suggestion or incentive that would have motivated the skilled artisan to modify Mayaud in the manner proposed by the action. See *In re Napier*, 55 F.3d 610, 633 (Fed. Cir. 1995). Thus, claim 2 is believed to be patentable.

Appln No. 09/650,482

Amdt date December 10, 2003

Reply to Office action of September 10, 2003

Claim 3 recites a plurality of customer records, each customer record including contact and formulary information for at least one customer. The action, on page 5, indicates that Mayaud teaches these features and cites col. 16, lines 18-49. However, Mayaud, in col. 6, lines 18-49, at most describes that "source database proprietors can remain wardens of the only copy of that data and obtain patient authorization to be the sole repository of that data" and referring to a "patient selection screen ... the name, age, gender, and social security numbers of patients who have authorized the user physicians to treat them, or to access the system on their behalf, are listed."

Thus, Mayaud, as cited above, describes "source database proprietors" and "a patient selection screen" and does not describe or suggest customer information including contact and formulary information for a customer or a plurality of customer records each including customer information. Accordingly, a *prima facie* case of obviousness cannot be established because the fundamental features recited in claim 3 is absent and not suggested in the cited references. Also, none of the cited references contain any suggestion or incentive that would have motivated the skilled artisan to modify Mayaud in the manner proposed by the action. See *In re Napier*, 55 F.3d 610, 633 (Fed. Cir. 1995). Thus, claim 3 is believed to be patentable.

Claim 6 recites that the pharmacy client system is configured to provide updates to the patient, customer, and formulary records in the global database. The action on page 6 indicates that Mayaud teaches these features and cites col. 31,

Appln No. 09/650,482

Amdt date December 10, 2003

Reply to Office action of September 10, 2003

lines 50-67 and col. 32, lines 1-36. However, Mayaud, in col. 31, lines 50-67 and col. 32, lines 1-36, at most describes an "allergies review" in which "allergy information is preferably an adjunct to her patient record and is downloaded to the user device from the host computer facility when Mary Harrington is selected" and "an alert screen can tell the physician of an allergy if an attempt is made to prescribe an offending drug."

Accordingly, Mayaud does not describe or suggest the pharmacy client system is configured to provide updates to the patient, customer, and formulary records in the global database as provided for in claim 6 and thus a *prima facie* case of obviousness cannot be established because the fundamental features recited in claim 6 is absent and not suggested in the cited references. Also, none of the cited references contain any suggestion or incentive that would have motivated the skilled artisan to modify Mayaud in the manner proposed by the action. See *In re Napier*, 55 F.3d 610, 633 (Fed. Cir. 1995). Hence, claim 6 is believed to be patentable.

Claim 7 recites that "updates to the formulary records include modification to the ingredients of the medication." The action on page 6 indicates that Mayaud teaches these features and cites col. 36, lines 1-9, col. 35, lines 44-67 and fig. 11 (128 & 130). However, Mayaud, col. 36, lines 1-9, col. 35, lines 44-67 and fig. 11 (128 & 130), at most describes "providing computer access of remote databases containing the information and by presenting available formulary drugs in a form which is easy for a physician to use, reference and prescribe" and that "physicians do not have to attempt to

Appln No. 09/650,482

Amdt date December 10, 2003

Reply to Office action of September 10, 2003

remember drug formularies and formularies may be changed with instant effect on all users without having physicians relearn the formulary."

Mayaud, however, does not describe or suggest the pharmacy client system is configured to provide updates to the formulary records which includes the modification to the ingredients of the medication as provided for in claim 7 and thus, a *prima facie* case of obviousness cannot be established. Also, none of the cited references contain any suggestion or incentive that would have motivated the skilled artisan to modify Mayaud in the manner proposed by the action. See *In re Napier*, 55 F.3d 610, 633 (Fed. Cir. 1995). Hence, claim 7 is believed to be patentable.

Claim 8 recites that updates to the modification to the ingredients of the medication include changes to amounts of caloric content in the medication and **claim 9** recites updates to the modification to the ingredients of the medication include changes to amounts and preferences of electrolytes in the medication.

The action on page 6 indicates that with respect to claim 8, Mayaud and Evans do not teach these features and that with respect to claim 9, this dependent claim is rejected for the similar rationale given for claim 8. However, the action states that "Official Notice is taken that it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the modifications to the ingredients of the medication include modifications to electrolytes in the medication because such a modification in Mayaud and Evans would

Appln No. 09/650,482

Amdt date December 10, 2003

Reply to Office action of September 10, 2003

allow Mayaud and Evans to have substances that dissociate into two or more ions, to some extent, in water." Applicant respectfully traverses this assertion and requests that a reference be cited in support of this position pursuant to MPEP § 2144.03 or withdrawal of these rejections.

"It would not be appropriate for the examiner to take official notice of facts without citing a prior art reference where the facts asserted to be well known are not capable of instant and unquestionable demonstration as being well-known." (See MPEP § 2144.03). Here, the Action simply takes Official notice that it is obvious that "modifications to the ingredients of the medication include modifications to electrolytes in the medication because such a modification in Mayaud and Evans would allow Mayaud and Evans to have substances that dissociate into two or more ions, to some extent, in water." However, the Action fails to cite any objective evidence that such knowledge actually exists or is instant and unquestionable. Also, even with such knowledge, the Action does not describe how to modify the ingredients of the medication to include changes to amounts of caloric content in the medication or to include changes to amounts and preferences of electrolytes or that such features or knowledge is instant and unquestionable.

"It is never appropriate to rely solely on "common knowledge" in the art without evidentiary support in the record, as the principal evidence upon which a rejection was based. *Zurko*, 258 F.3d at 1385, 59 USPQ2d at 1697 ("[T]he Board cannot simply reach conclusions based on its own understanding or experience-or on its assessment of what would be basic knowledge or common sense. Rather, the Board must point to some concrete

Appln No. 09/650,482

Amdt date December 10, 2003

Reply to Office action of September 10, 2003

evidence in the record in support of these findings.")." (See MPEP 2144.03).

Thus, in the absence of specific evidence that updates to the modification to the ingredients of the medication include changes to amounts of caloric content in the medication or include changes to amounts and preferences of electrolytes in the medication would be obvious to a person of ordinary skill in the art, the rejection based on "general knowledge" or "common sense" is improper. See *In re Lee*, 61 U.S.P.Q. 2d 1430, 1435 (Fed. Cir. 2002) and MPEP 2144.03. Instead, the action must articulate, and place on the record, any knowledge to which it refers. *Id.*

Furthermore, the only suggestion for the claimed combination of elements comes directly from Applicant's own specification. Thus, it appears that impermissible hindsight reconstruction has been used in applying the cited references and official notice, using the claimed invention as an instruction manual to piece together the claimed invention.

Accordingly, Applicants respectfully request withdrawal of the rejection or requests the reference that supports the Action's cited position and in particular the reference that describes the features as applied to claims 8 and 9.

Claim 10 recites the pharmacy client system is configured to verify the updates to the formulary records in the global database. The action on page 6 indicates that Mayaud teaches these features and cites col. 6, lines 59-67 and col. 7, lines 1-2 and lines 30-45. However, Mayaud, in col. 6, lines 59-67 and col. 7, lines 1-2, at most describes "FIG. 16 is a schematic

Appln No. 09/650,482

Amdt date December 10, 2003

Reply to Office action of September 10, 2003

diagram of one way of connecting users of the prescription management system of FIGS. 1-14 with remote source databases across network to provide data and processing resources needed during operation of the prescription management system and useful inter alia for creation of a virtual patient record; FIG. 17 is a schematic block flow diagram showing a sequence of operating steps of the prescription creation system shown in FIGS. 1-11; FIG. 18 is a diagram similar to the diagram of FIG. 17, showing a condition driven drug selection procedure."

Mayaud, in col. 7, lines 30-45, also at most describes that a "host computer facility provides data, or access to data, data processing and communications resources for users to draw upon via the user interface devices ... can call upon a variety of external resources and functions as a marshalling and processing center for organizing resources into useful and manageable pieces for utilization by limited capacity user-interface devices ... is a co-ordination point on a network for a number of user-device clients" and "the network accesses or includes a number of remote database sources providing useful information elements to the system."

Mayaud, however, does not describe or suggest the pharmacy client system is configured to verify the updates to the formulary records in the global database as provided for in claim 10 and thus, a *prima facie* case of obviousness cannot be established. Also, none of the cited references contain any suggestion or incentive that would have motivated the skilled artisan to modify Mayaud in the manner proposed by the action. See *In re Napier*, 55 F.3d 610, 633 (Fed. Cir. 1995). Hence, claim 10 is believed to be patentable.

Appln No. 09/650,482

Amdt date December 10, 2003

Reply to Office action of September 10, 2003

Claim 11 recites that the medication specific label is for an intravenous solution and the medication identification information includes a refractive index associated with the intravenous solution, **claim 12** recites the medication specific label is for an intravenous solution and the medication identification information includes a level of potassium associated with the intravenous solution, and **claim 13** recites the pharmacy client system is configured to generate a calcium phosphate solubility curve for an order accepted and processed by the at least one pharmacy client.

The action on pages 7-8 indicates that with respect to claims 11-13, Mayaud and Evans do not teach the features recited in the claims. However, the action states that "Official Notice is taken." Applicant respectfully traverses this assertion and requests that a reference be cited in support of this position pursuant to MPEP § 2144.03 or withdrawal of these rejections.

"It would not be appropriate for the examiner to take official notice of facts without citing a prior art reference where the facts asserted to be well known are not capable of instant and unquestionable demonstration as being well-known." (See MPEP § 2144.03). Here, the Action simply takes Official notice "that it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the medication specific labels for the medication include information about a refractive index of the intravenous solution and to modify in Mayaud and Evans because such a modification in Mayaud and Evans would allow Mayaud and Evans to have information regarding the refractive index since the refractive

Appln No. 09/650,482

Amdt date December 10, 2003

Reply to Office action of September 10, 2003

index increases with the atomic number of constituent atoms in the" intravenous solution.

The action also takes Official notice "that it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the medication specific label for an intravenous solution and the medication identification information include a level of potassium associated with the intravenous solution and to modify in Mayaud and Evans because such a modification would allow Mayaud and Evans to use an intravenous solution for medical conditions such as dehydration to put the electrolytes back into a person's body."

Furthermore, the action take Official Notice "that it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the pharmaceutical system wherein the pharmacy client system is configured to generate a calcium phosphate solubility curve for an order accepted and processed by the at least one pharmacy client and to modify in Mayaud and Evans because such a modification would provide a time release of the compounds of calcium salts of phosphoric acid which are frequently used as calcium supplements."

However, in each case, the Action fails to cite any objective evidence that such knowledge actually exists or is instant and unquestionable. Also, even with such knowledge, the Action does not describe how to include a medication specific label for an intravenous solution, the medication identification information on the label with a refractive index or level of potassium associated with the intravenous solution, or to generate a calcium phosphate solubility curve for an order

Appln No. 09/650,482

Amdt date December 10, 2003

Reply to Office action of September 10, 2003

accepted and processed by a pharmacy client or that such features or knowledge is instant and unquestionable.

"It is never appropriate to rely solely on "common knowledge" in the art without evidentiary support in the record, as the principal evidence upon which a rejection was based. *Zurko*, 258 F.3d at 1385, 59 USPQ2d at 1697 ("[T]he Board cannot simply reach conclusions based on its own understanding or experience-or on its assessment of what would be basic knowledge or common sense. Rather, the Board must point to some concrete evidence in the record in support of these findings.")." (See MPEP 2144.03).

Thus, in the absence of specific evidence that medication specific label is for an intravenous solution, the medication identification information includes a refractive index or level of potassium associated with the intravenous solution or that a pharmacy client system is configured to generate a calcium phosphate solubility curve for an order accepted and processed by a pharmacy client would be obvious to a person of ordinary skill in the art at the time the invention was made, the rejection based on "general knowledge" or "common sense" is improper. See *In re Lee*, 61 U.S.P.Q. 2d 1430, 1435 (Fed. Cir. 2002) and MPEP 2144.03. Instead, the action must articulate, and place on the record, any knowledge to which it refers. *Id.*

Furthermore, the only suggestion for the claimed combination of elements comes directly from Applicant's own specification. Thus, it appears that impermissible hindsight reconstruction has been used in applying the cited references and official notice, using the claimed invention as an instruction manual to piece together the claimed invention.

Appln No. 09/650,482

Amdt date December 10, 2003

Reply to Office action of September 10, 2003

Accordingly, Applicants respectfully request withdrawal of the rejection or requests the reference that supports the Action's cited position and in particular the reference that describes the features as applied to claims 11-13.

Furthermore, as stated in the action, Mayaud and Evans do not teach the features recited in claim 11 and furthermore the action does not suggest the desirability of the modification or combination that the medication specific label is for an intravenous solution as provided for in claim 11 and thus, a *prima facie* case of obviousness cannot be established. Hence, claim 11 is believed to be patentable.

Moreover, as stated in the action, Mayaud and Evans do not teach the features recited in claim 13 and furthermore the action does not suggest the desirability of the modification or combination that a pharmacy client system is configured to generate a calcium phosphate solubility curve for an order accepted and processed by the at least one pharmacy client as provided for in claim 13 and thus, a *prima facie* case of obviousness cannot be established. Hence, claim 13 is believed to be patentable.

Claim 14 recites a backup network including a backup server, the service center server replicating records of orders for medication and providing the records replicated to the backup server, the backup server storing the records replicated in a backup database and providing access to the backup database by the pharmacy network when the service center network is not available for a predetermined amount of time. The action on page

Appln No. 09/650,482

Amdt date December 10, 2003

Reply to Office action of September 10, 2003

8 indicates that Mayaud teaches these features and cites col. 17, lines 44-52, col. 46, lines 16-31 and fig. 16.

However, the cited portions in Mayaud do not describe or suggest a backup network including a backup server, the service center server replicating records of orders for medication and providing the records replicated to the backup server, the backup server storing the records replicated in a backup database and providing access to the backup database by the pharmacy network when the service center network is not available for a predetermined amount of time as provided for in claim 14 and thus, a *prima facie* case of obviousness cannot be established. Also, none of the cited references contain any suggestion or incentive that would have motivated the skilled artisan to modify Mayaud in the manner proposed by the action. See *In re Napier*, 55 F.3d 610, 633 (Fed. Cir. 1995). Hence, claim 14 is believed to be patentable.

Claim 15 recites the pharmacy server is configured with a local database containing a subset of formulary records of the plurality of formulary records in the global database that specifically pertains to the pharmacy network.

The action on page 8 indicates that Mayaud teaches these features and cites col. 17, lines 44-52, col. 46, lines 16-31 and fig. 16. However, the cited portions in Mayaud do not describe or suggest that a pharmacy server is configured with a local database containing a subset of formulary records of the plurality of formulary records in the global database that specifically pertains to the pharmacy network as provided for in claim 15 and thus, a *prima facie* case of obviousness cannot be

Appln No. 09/650,482

Amdt date December 10, 2003

Reply to Office action of September 10, 2003

established. Also, none of the cited references contain any suggestion or incentive that would have motivated the skilled artisan to modify Mayaud in the manner proposed by the action. See *In re Napier*, 55 F.3d 610, 633 (Fed. Cir. 1995). Hence, claim 15 is believed to be patentable.

Claims 16-27

On page 8 of the action, claims 16-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,758,095 issued to Albaum and U.S. Patent No. 5,737,539 issued to Edelson et al. ("Edelson"). Applicant respectfully traverses this rejection.

The action indicates that Albaum teaches the pharmaceutical administrative system of claim 1, but fails to provide any specific reference in Albaum that describes the features recited in claim 1. However, Albaum does not appear to teach or suggest the features recited in claim 1, such as a pharmacy network, a service center network and a service center server that supplies the pharmacy server one of a plurality of formulary records upon request by a pharmacy client system when an order is processed.

Also, the action indicates that Albaum teaches "a customer unit coupled to the order maintenance unit and presenting information relating to contact and purchasing information for the at least one customer ordering the medication (col. 7, lines 7-24; and a patient unit coupled to the order maintenance unit and the customer unit and presenting information relating to contact and medical information for the at least one patient (col. 10, lines 18-43)).

Appln No. 09/650,482

Amdt date December 10, 2003

Reply to Office action of September 10, 2003

However, Albaum, in col. 7, lines 7-24, at most describes that "an inpatient module 13 which permits the system to interface with a preexisting hospital pharmacy system 12. Patient admission, discharge and transfer (ADT) information can flow from the ADT unit interface 14 directly to the inpatient module 13 or via the pre-existing hospital pharmacy system 12. ADT data includes patient name, medical record number, account numbers, address, date of birth, allergies, physicians, insurance information, clinic information, nursing station and bed number."

Albaum, however, does not describe or suggest a customer unit coupled to the order maintenance unit and presenting information relating to "contact and purchasing information for the at least one customer ordering the medication" as recited in claim 16. Also, since Albaum does not describe or suggest the customer unit as noted above, Albaum does not describe or suggest a patient unit coupled to the customer unit as provided for in claim 16.

Furthermore, the action indicates that "Albaum did not teach, wherein the order maintenance unit is configured to modify the ingredients of the medication and to validate the modifications to the ingredients of the medication." The action also suggests that "Edelson discloses, wherein the order maintenance unit is configured to modify the ingredients of the medication and to validate the modifications to the ingredients of the medication (col. 12, lines 42-65).

However, Edelson, in col. 12, lines 42-65, at most describes for example "the system may prompt the user that the last time Drug X was prescribed for Condition Y, Patient Q

Appln No. 09/650,482

Amdt date December 10, 2003

Reply to Office action of September 10, 2003

reported adverse reaction Z. Where the host computer facility documents a catalog of known adverse reactions to system-listed drugs, a system enhancement can report new adverse reactions to the user or centrally ... by tracking logged patient conditions and relating them, where appropriate, to a previous prescription. In similar manner the system may log drug-drug interactions" and many "other valuable retrospective statistical studies and analyses are made possible by deployment of the invention."

Edelson, however, does not describe or suggest an order maintenance unit configured to "modify the ingredients of the medication" and "to validate the modifications to the ingredients of the medication" as provided for in claim 16. Accordingly, a *prima facie* case of obviousness cannot be established because the fundamental features recited in claim 16 is absent and not suggested in the cited references.

Furthermore, individually, each of the references provides a complete solution. Specifically, Albaum provides a complete solution to provide ordering and prescribing drugs for a patient. Likewise, Edelson, provides a complete solution to provide an electronic prescription creation system. Hence, there is no motivation, suggestion or teaching to improve upon the complete solutions of Albaum or Edelson to arrive at the claimed invention. Moreover, there is no teaching or suggestion as to how to combine the medication ordering system of Albaum with the electronic prescription creation system of Edelson to result in the claimed invention, specifically as recited in claim 16.

Appln No. 09/650,482

Amdt date December 10, 2003

Reply to Office action of September 10, 2003

The action, on page 10, also indicates that Albaum disclosures, "wherein the order maintenance unit is configured to modify the ingredients of the medication and to validate the modifications to the ingredients of the medication (col. 10, lines 44-67)." This contradicts the statement noted above on page 9 of the action that "Albaum did not teach wherein the order maintenance unit is configured to modify the ingredients of the medication and to validate the modifications to the ingredients of the medication." In any event, Albaum, in col. 10, lines 44-67, does not teach or suggest an order maintenance unit configured to "modify the ingredients of the medication" and to "validate the modifications to the ingredients of the medication" as recited features in claim 16. Therefore, for all the reasons set forth above, claim 16 is believed to be patentable.

Since claims 17-27 depend respectively from claim 16 which depends from independent claim 1 and thus incorporate the features recited in these claims and contain additional limitations that, when considered as a whole are patentably distinguishable over the references of record, claims 17-27 are also believed to be patentable.

Also, regarding **claims 18-23 and 26-27**, the action on pages 10-13 indicates that, Albaum and Edelson do not teach the features recited in the claims. However, the action liberally states that "Official Notice is taken" for each respective claim. Applicant respectfully traverses each assertion in claims 18-23 and 26-27 and requests that a reference be cited in

Appln No. 09/650,482

Amdt date December 10, 2003

Reply to Office action of September 10, 2003

support of each position pursuant to MPEP § 2144.03 or withdrawal of these rejections.

"It would not be appropriate for the examiner to take official notice of facts without citing a prior art reference where the facts asserted to be well known are not capable of instant and unquestionable demonstration as being well-known." (See MPEP § 2144.03). Here, with respect to claim 18, the Action simply takes Official notice "that it would have been obvious to one having ordinary skill in the art at the time the invention was made to have an order maintenance unit configured to validate the modifications to the ingredients by generating a calcium phosphate solubility curve for the medication and to modify in Albaum and Edelson because such a modification would provide a time release of the compounds of calcium salts of phosphoric acid which are frequently used as calcium supplements." With respect to claims 19-20, the action indicates that these dependent claims are rejected for the similar rationale given for respective claims 18 and 18-19.

With respect to claim 21, the action also takes Official notice "that it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the order maintenance unit configured to generate medication specific labels for the medication and to modify in Albaum and Edelson because such a modification in Albaum and Edelson would allow Albaum and Edelson to have a prescription delivery system to generate the invoice and label and other documentation prior to delivering the medication to the patient."

With respect to claim 22, the action also simply takes Official notice "that it would have been obvious to one having

Appln No. 09/650,482

Amdt date December 10, 2003

Reply to Office action of September 10, 2003

ordinary skill in the art at the time the invention was made to have the medication specific labels for the medication include information about a refractive index of the intravenous solution and to modify in Albaum and Edelson because such a modification in Albaum and Edelson would allow Albaum and Edelson to have information regarding the refractive index since the refractive index increases with the atomic number of constituent atoms in the" intravenous solution.

With respect to claim 23, the action also takes Official notice "that it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the medication specific labels for the medication include information about a level of potassium in the intravenous solution calculated using flame photometry and to modify in Albaum and Edelson because such a modification would allow Albaum and Edelson to have a major intracellular cation that is widely distributed in the body in muscle tissue, nerve tissue, blood cells, and plasma which is filtered in the glomerulus, absorbed in the proximal tubule and finally excreted by exchange for sodium in the distal tubule. The reliability of the results depends on the proper maintenance of the flame photometer and salient features. If low serum potassium values are observed due to low intake of dietary potassium over a period of time or increased loss through kidney, vomiting or diarrhea and increased secretion of adrenal steroids or some diuretics that promote the loss of potassium a flame photometer (digital flame photometer) for simultaneous measurement is useful in these medical conditions."

Appln No. 09/650,482

Amdt date December 10, 2003

Reply to Office action of September 10, 2003

With respect to claim 26, the action also takes Official notice "that it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the modifications to the ingredients of the medication include modifications to electrolytes in the medication and to modify in Albaum and Edelson because such a modification would allow Albaum and Edelson to have substances that dissociate into two or more ions, to some extent, in water." With respect to claim 27, the action indicates that this dependent claim is rejected for the similar rationale given above for claim 26.

However, in each case, the Action fails to cite any objective evidence that such knowledge actually exists or is instant and unquestionable. Also, even with such knowledge, the Action does not describe how to provide these features in Albaum or Edelson, which do not contemplate any of these features, or that such features or knowledge is instant and unquestionable.

"It is never appropriate to rely solely on "common knowledge" in the art without evidentiary support in the record, as the principal evidence upon which a rejection was based. *Zurko*, 258 F.3d at 1385, 59 USPQ2d at 1697 ("[T]he Board cannot simply reach conclusions based on its own understanding or experience-or on its assessment of what would be basic knowledge or common sense. Rather, the Board must point to some concrete evidence in the record in support of these findings.")." (See MPEP 2144.03).

Thus, in the absence of specific evidence the above recited features in claims 18-23 and 26-27 would be obvious to a person of ordinary skill in the art at the time the invention was made, the rejection based on "general knowledge" or "common sense" is

Appln No. 09/650,482

Amdt date December 10, 2003

Reply to Office action of September 10, 2003

improper. See *In re Lee*, 61 U.S.P.Q. 2d 1430, 1435 (Fed. Cir. 2002) and MPEP 2144.03. Instead, the action must articulate, and place on the record, any knowledge to which it refers. *Id.*

Furthermore, the only suggestion for the claimed combination of elements comes directly from Applicant's own specification. Thus, it appears that impermissible hindsight reconstruction has been used in applying the cited references and official notice, using the claimed invention as an instruction manual to piece together the claimed invention.

Accordingly, Applicants respectfully request withdrawal of the rejection or requests the reference that supports the Action's cited position and in particular the reference that describes the features as applied to claims 18-23 and 26-27.

Claim 24 recites that the modifications to the ingredients of the medication includes modifications to caloric content of the medication. **Claim 25** recites that the order maintenance unit is configured to validate the modifications to the caloric content in the medication by comparing the modifications to predetermined amounts of caloric content in predefined medications.

The action on page 8, with respect to claim 24, indicates that Albaum teaches the features in claim 24 and cites col. 10, lines 17-43 and with respect to claim 25, indicates that this dependent claim is rejected for the similar rationale given above for claim 24.

However, the cited portions in Albaum do not describe or suggest that the modifications to the ingredients of the medication includes modifications to caloric content of the

Appln No. 09/650,482

Amdt date December 10, 2003

Reply to Office action of September 10, 2003

medication or that the order maintenance unit is configured to validate the modifications to the caloric content in the medication by comparing the modifications to predetermined amounts of caloric content in predefined medications as provided for in respective claims 24 and 25. Also, none of the cited references contain any suggestion or incentive that would have motivated the skilled artisan to modify Albaum in the manner proposed by the action. See *In re Napier*, 55 F.3d 610, 633 (Fed. Cir. 1995). Thus, a *prima facie* case of obviousness cannot be established and accordingly claims 24-25 are believed to be patentable.

In view of the foregoing remarks, it is respectfully submitted that this application is now in condition for allowance. Accordingly, reconsideration of the application and allowance of claims 1-27 are respectfully requested. If the Examiner should have any remaining questions or objections, a telephone interview to discuss and resolve these issues is respectfully requested.

Respectfully submitted,
CHRISTIE, PARKER & HALE, LLP

By 

Patrick Y. Ikehara

Reg. No. 42,681

626/795-9900

PYI/pyi

RMW IRV1072469.1--12/10/03 11:58 AM